510(k) Summary
Small PLATEAU® (PLATEAU-C) Spacer System

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Date Prepared: October 5th, 2010

Trade Name: Plateau-C Spacer System

Common Name: Intervertebral Body Fusion Device

Classification: ODP, 21 CFR 888.3080, Class II

Device Description:

The Small PLATEAU Spacer System is intended to serve as an intervertebral body fusion device. The implant is available in a range of sizes and footprints to suit the individual pathology and anatomical conditions of the patient. It is fabricated and manufactured from Polyetheretherketone (PEEK-OPTIMA LT1) with radiographic markers. The implant is hollow to permit packing with bone graft to help promote intervertebral body fusion. The superior and inferior surfaces have teeth to assist in the interface with the vertebral endplates to prevent rotation and/or migration.

Intended Use of the Device:

The Small PLATEAU Spacer System is intended for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one disc level (C2-T1). DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. It is to be used in patients who have had at least six weeks of non-operative treatment. This device is intended to be used with autogenous bone graft and a supplemental internal spinal fixation system.

Performance Data:

Biomechanical testing in accordance with ASTM standards was conducted to demonstrate substantial equivalence to the predicate intervertebral body fusion devices.

Test Data

Invibio, the manufacturer and supplier of the raw PEEK-OPTIMA material, has proven biocompatibility for implantable contact greater than 30 days to the ISO 10993 standard. Independent laboratories have performed the relevant ISO 10993 testing to ensure that PEEK-OPTIMA is a biocompatible material. Invibio has device master files MAF 1209 containing the ISO 10993 testing as well as additional testing and extensive data concerning the polymer and its manufacturing methods, lodged with the Food and Drug Administration. Life Spine has been granted access letters for these files. These access letters can be found in Appendix H.

In addition, biomechanical testing was conducted to demonstrate substantial equivalency of the Small PLATEAU Spacer System to the predicate devices. Static axial compression, static expulsion, static subsidence, static torsion, dynamic axial compression, and dynamic torsion tests were performed on 14mm x 11mm x 14mm, 7° implants, which was determined to be the optimal size implant to match the predicate testing as outlined in ASTM F2077 and F2267.

This construct was determined to be the worst case construct as the cross sectional area of these implants does not change as the height changes. Additionally, this configuration of the Small PLATEAU Spacer System embodies the worst case scenario wall thickness and therefore represents the worst case construct for testing.

The worst case scenario constructs per ASTM F2077 and F2267 guidelines were assembled at Empirical Testing, an independent testing facility. The results of these tests can be found in Empirical Testing Technical Report #199-534806-115 in Appendix B.

The test results demonstrate that the Small PLATEAU Spacer System is substantially equivalent to the predicate devices.

Substantial Equivalence:

Equivalent Products

The Small PLATEAU Spacer System is substantially equivalent to the Spinal Elements Crystal (K073351), the US Spine Phantom Plus Cage System (K082801), and the DePuy Bengal System (K081917).

Equivalency

Based upon the information presented in the Summary of Design Comparison Table (Table 1) below, the Small PLATEAU Spacer System is substantially equivalent in design, materials, function and indications for use to the predicate devices presented.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 13 2010

Life Spine, Inc.
% Mr. Randy Lewis
2401 West Hassell Road, Suite 1535
Hoffman Estates, Illinois 60169

Re: K093093
Trade/Device Name: Small PLATEAU® (PLATEAU-C) Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: October 05, 2010
Received: October 06, 2010

Dear Mr. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

Indications for Use

510(k) Number: K093093

Device Name: Small PLATEAU® (PLATEAU-C) Spacer System

Indications for Use: The Small PLATEAU Spacer System is intended for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one disc level (C2-T1). DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. It is to be used in patients who have had at least six weeks of non-operative treatment. This device is intended to be used with autogenous bone graft and a supplemental internal spinal fixation system.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093093